

AMENDMENTS TO THE CLAIMS

1. (Original) A paclitaxel composition for the treatment of bladder tumor via intravesical administration, comprising 4 ~ 90 % by weight of at least one monoglyceride compound, 0.01 ~ 90 % by weight of at least one oil, 0.01 ~ 90 % by weight of at least one emulsifier and 0.01 ~ 20 % by weight of paclitaxel.
2. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 1, wherein said monoglyceride is ~~selected from a group consisting of~~ chosen from saturated or unsaturated monoglyceride compounds having 10 ~ 22 carbon atoms in the hydrocarbon chain.
3. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 2, wherein said monoglyceride compound is ~~selected from a group consisting of~~ chosen from monoolein, monopalmitolein, monomyristolein, monoelaidin, and monoerucin, or from a group consisting of the a mixture of monoglycerides semi-synthesized from triglycerides of vegetable or and animal oil.
4. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 1, wherein said oil is ~~selected from a group consisting of~~ chosen from triglyceride, iodized oil, vegetable oil and animal oil.
5. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 4, wherein said triglyceride is ~~selected from a group consisting of~~ chosen from saturated and unsaturated triglycerides having 2 ~ 20 carbon atoms in each hydrocarbon chain.
6. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 4 5, wherein said triglyceride is ~~selected from a group consisting of~~ chosen from triacetin, tributyrin, tricaproin, tricaprylin, tricaprin and triolein; wherein said

iodized oil is chosen from Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil; wherein said vegetable oil is chosen from soybean oil, cottonseed oil, olive oil, poppyseed oil, linseed oil and sesame oil; and wherein said animal oil is chosen from squalane and squalene.

7. – 9. (Canceled)

10. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 1, wherein said emulsifier is selected chosen from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and bile acid.

11. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 10, wherein said phospholipid is selected from the group consisting of a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative, and a polymeric lipid wherein a hydrophilic polymer is conjugated to the lipid headgroup; wherein said non-ionic surfactant is chosen from a poloxamer (Pluronic: polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij); wherein said anionic surfactant is chosen from a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative and sodium dodecyl sulfate (SDS); wherein said cationic surfactant is chosen from 1,2-dioleyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-[1-(1,2-dioleyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA), 1,2-dioleyl-3-ethylphosphocholic acid (DOEPC) and 3 $\beta$ -[N-[N',N'-dimethylamino)ethan]carbamoyl]cholesterol (DC-Chol); and wherein said bile acid is chosen from cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

12. – 15. (Canceled)

16. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 1, additionally comprising 0.01 ~ 5 % by weight of other additives another additive.

17. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 16, wherein ~~said other additives are selected from the group consisting of the other additive chosen from Cremophor, tocopherol, tocopherol acetate, fatty acids, fatty acid esters, fatty acid alcohols, insoluble drugs, alcohols and polyols.~~

18. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 17, wherein said insoluble drugs are ~~selected from the group consisting of chosen from anticancer drugs, p-glycoprotein inhibitors and hepatic metabolism blockers; wherein said alcohols are chosen from methanol, ethanol, propanol and isopropanol; and wherein said polyols are chosen from ethyleneglycol, propyleneglycol and polyethyleneglycol.~~

19. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 18, wherein said anticancer drugs are ~~selected chosen from the group consisting of doxorubicin, cisplatin, carboplatin, carmustin (BCNU), dacarbazine, etoposide, 5-fluorouracil and paclitaxel derivatives wherein said paclitaxel derivatives are chosen from docetaxel, bromotaxel and taxotere; wherein said p-glycoprotein inhibitors are chosen from cinchonins, calcium channel blockers, calmodulin antagonists, Vinca alkaloids, antiarrhythmics, steroids, antihypertension drugs, anthelmintics and immunosuppressants; and wherein said hepatic metabolism blockers are chosen from anticancer drugs including cyclosporin A, doxorubicin, etoposide (VP-16) and cisplatin; verapamil; and tamoxifen.~~

20 - 21. (Canceled)

22. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 19 21, wherein said calcium channel blockers are dihydropyridines ~~selected from the group consisting of chosen from verapamil, nifedipine, nicardipine and nitrendipine; wherein calmodulin antagonist is trifluoroperazine; wherein antihypertension drug is reserpine; wherein Vinca alkaloids are chosen from vincristine and vinblastine; wherein steroid is progesterone; wherein said antiarrhythmics are chosen from amiodarone and quinidine; wherein said anthelmintics are chosen from quinacrine and quinine; and wherein said immunosuppressants are selected from the group consisting of cyclosporins, staurosporin and tacrolimus.~~

23. – 32. (Canceled)

33. (Currently Amended) A method of preparing the paclitaxel composition for the treatment of bladder tumor via intravesical administration according to ~~any one of~~ Claims 1 through 32,

wherein said method comprises the steps of:

1) preparing the viscous liquid by mixing 4 ~ 90% by weight of at least one monoglyceride compound, 0.01 ~ 90 % by weight of at least one oil and 0.01 ~ 90 % by weight of at least one emulsifier at ~~temperatures~~ temperatures lower than 50 °C (step 1); and

2) preparing homogeneous mixture by solubilizing completely 0.01 ~ 20 % by weight of paclitaxel in said mixture in step (1) (step 2).

34. (Original) The method of preparing the paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 33, wherein the said mixture is heated to 50 °C in step (1) to speed up the solubilization process.

35. (Original) The method of preparing the paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 33, wherein the said mixture is heated to 50 °C or sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

36. (Currently Amended) A method of preparing the paclitaxel composition for the treatment of bladder tumor via intravesical administration according to ~~any one of~~ Claims 1 through 32, wherein said method comprises the steps of:

1) preparing the paclitaxel solution by solubilizing 0.01 ~ 20% by weight of paclitaxel in 0.01 ~ 90 % by weight of at least one oil by sonicating in a bath type sonicator (step 1); and

2) preparing homogeneous mixture by mixing the paclitaxel solution in step (1) and 0.01 ~ 90 % by weight of at least one emulsifier and 4 ~ 90 % by weight of monoglyceride (step 2).

37. (Original) The method of preparing the paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 36, wherein the said mixture is heated

to 50 °C and sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

38. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to ~~any one of~~ Claims 1 ~~through~~ 32, wherein said composition is administered intravesically after transurethral resection to treat superficial or invasive bladder tumor.

39. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to ~~any one of~~ Claims 1 ~~through~~ 32, wherein said composition is allowed to stay at least 2 hours after intravesical administration of 10 ~ 100 ml through the urethral catheter after reducing the amount of urine to or less than 10 ml.

40. (Original) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 39, wherein the method of controlling the production rate of urine to 1 ml/min or less additionally employed.

41. (Original) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 39, wherein said composition is administered intravesically more than one time.

42. (Original) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to Claim 39, wherein said composition is administered intravesically for more than 6 weeks.

43 42. (Currently Amended) The paclitaxel composition for the treatment of bladder tumor via intravesical administration according to ~~any one of~~ Claims 1 ~~through~~ 32, wherein said bladder tumor is Ta, T1 or Tis.